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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,577	11/13/2003	Stefan Berg	1103326-0525 DIV	1754
7470	7590	06/22/2005	EXAMINER	
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,577

Applicant(s)

BERG ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the response filed 4/29/2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7,9,10,12,13 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7, 9, 10, 12, 13, 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 2, 4, 7, 9, 10, 12, 13, 27-30 are pending.

The rejection of claims 1 and 6 over 35 USC 112 stands over claim 1. Claim 6 has been deleted.

It is immaterial that the compounds that were provisoed out were in the parent application.

The claims as written do not have any enablement and written description for the hetero groups now claimed. There is no disclosed species, other than the ones claimed in the parent.

And there is no written description as to what these other hetero groups are.

Thus the rejection still stands.

The rejection of claim 1 under 35 USC 112 second para has been withdrawn since applicants do have a description on page 5 of the specifications.

The rejection on claims 25 and 26 are withdrawn since applicants have cancelled the claims.

The rejection of claims 13, 27–28 under 35 USC 112 still stands. The claims recite treatment of 5-hydroxytryptamine –mediated disorder. This is a claim drawn to a specific mechanism and the diseases it would treat. The list of diseases treatable by a mechanism may be different a few years from now since some more diseases may be discovered to have the same mechanism associated with it. Drugs also do not act as agonists and antagonists. It is either one or the other. Thus drugs that treat depression may not be able to treat anxiety. The specifications do not have any enablement as to which diseases it would treat. Applicants may be able to overcome this by inserting within the claim “wherein the disorder is depression”

The double patenting rejection over US 6479497 still stands. Even though the applicants have amended the claim to be “is mono substituted” the prior patent in its “may be mono

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substituted" covers the scope of the applicants compounds. Even the hetero substitutions on the phenyl R3 are encompassed by the prior patent.

Hence the rejection still stands.

The restriction made in the parent was as follows

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

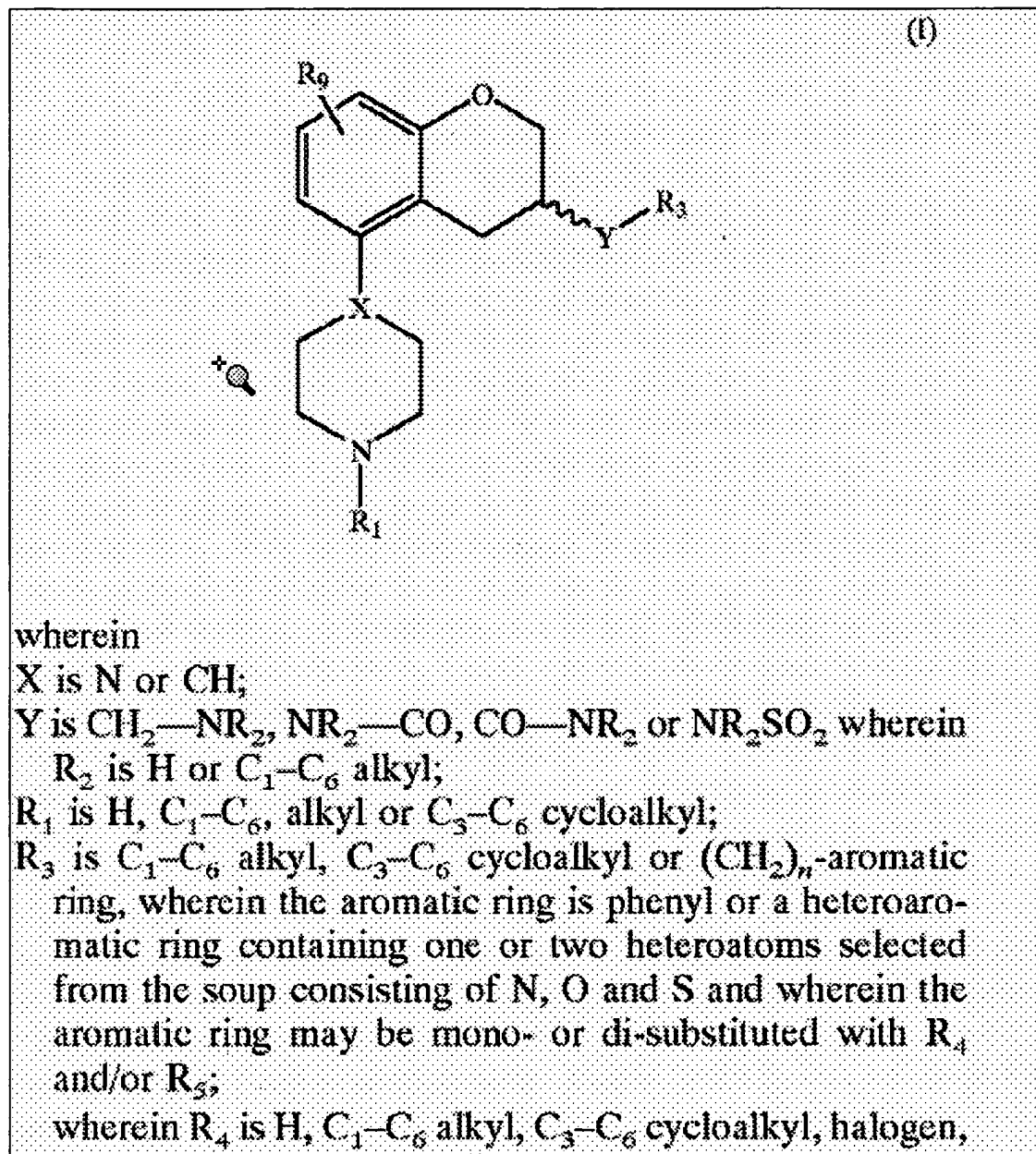
- I. Claims 1,2,4-10,12,13,27,28 and 29A(i), (ii), drawn to compounds, pharmaceutical compositions and a method of treating, wherein R3 is an alkyl, classified in class 546, 514 subclass 196,320.
- II. Claims 1,2,4-10,12,13,27,28 and 29A(i), (ii), drawn to compounds, pharmaceutical compositions and a method of treating, wherein R3 is a cycloalkyl, classified in class 546, 514, subclass 196,320.
- III. Claims 1,2,4-10,12,13,27,28 and 29A(i), (ii), drawn to compounds, pharmaceutical compositions and method of treating wherein R3 is a -(CH2)-phenyl, classified in class 546, 514, subclass 196,320. A further election of a single disclosed species is required. [Applicants elected a species as given on page 6, lines 16-17].
- IV. Claims 1,2,4-10,12,13,27,28 and 29A(i), (ii), drawn to compounds, pharmaceutical compositions and a method of treating, wherein R3 is hetero ring, classified in various classes and subclasses.
- V. Claims 25, 26, drawn to different methods of treating, classified in class 514 and various subclasses.
- VI. Claim 29 A(iii), Bi), Bii), drawn to different processes of making these compounds, classified in various classes and subclasses.
- V. Claim 30, drawn to a different core, classified in various classes and subclasses.

applicants seem to have elected group III over again.

The D. P. rejection still stands.

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Even the rejection of claims 1, 2, 4, 7, 9, 10, 12, 13, 27-30 over US 6387899 still stands since there is clearly overlapping subject matter. There is overlapping subject matter



As given above X can be N, Y can be NR_2CO or CO R_2 or $\text{CH}_2 \text{NR}_2$, NR_2SO_2 , R_3 is a CH_2n -aromatic ring which may be mono or di substituted.

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Thus there is clearly overlap.

Claims 30 rejection over US 6384225 has been withdrawn since the patent compounds teach the compounds with the R9 on its ring.

Conclusion

Claims 1, 2, 4, 7, 9, 10, 12, 13, 27-30 are still rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
June 17, 2005

R. Desai
6/20/05